UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,125	12/22/2003	Peter M. Bonutti	2500DV2CN2DV3CN6	7494
50855 Tyco Healthcar	7590 05/28/200 e Group L.P	EXAMINER		
60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473			KASZTEJNA, MATTHEW JOHN	
NORTH HAVEN, CT 004/3			ART UNIT	PAPER NUMBER
			3739	
			MAIL DATE	DELIVERY MODE
			05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/743,125	BONUTTI, PETER M.			
Office Action Summary	Examiner	Art Unit			
	MATTHEW J. KASZTEJNA	3739			
The MAILING DATE of this communication Period for Reply	n appears on the cover sheet with	the correspondence address			
A SHORTENED STATUTORY PERIOD FOR RI WHICHEVER IS LONGER, FROM THE MAILIN - Extensions of time may be available under the provisions of 37 Cf after SIX (6) MONTHS from the mailing date of this communicatio - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by s Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	G DATE OF THIS COMMUNICA FR 1.136(a). In no event, however, may a rep n. eriod will apply and will expire SIX (6) MONTH statute, cause the application to become ABAI	ATION. ly be timely filed HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).			
Status					
1) ■ Responsive to communication(s) filed on general condition is FINAL . 2b) □ Since this application is in condition for all closed in accordance with the practice under the condition is the condition of the closed in accordance with the practice.	This action is non-final. owance except for formal matter	-			
Disposition of Claims					
4) ☐ Claim(s) 11-15 and 22-29 is/are pending in 4a) Of the above claim(s) is/are with 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 11-15 and 22-29 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction a	ndrawn from consideration.				
Application Papers					
9) ☐ The specification is objected to by the Example 10) ☑ The drawing(s) filed on 12/22/03 is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the control of the contr	☑ accepted or b)☐ objected to the drawing(s) be held in abeyance prrection is required if the drawing(s	e. See 37 CFR 1.85(a).) is objected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	B) Paper No(s)/	mmary (PTO-413) Mail Date ormal Patent Application			

Art Unit: 3739

DETAILED ACTION

Page 2

Notice of Amendment

In response to the amendment filed on February 4, 2008, amended claims 1 and 25 and new claims 28-29 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, and 11 of copending Application No. 10/729,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 11 of copending Application No. 10/729,634.

Claims 1 and 11 of copending application No. 10/729,634 recite a retractor comprised of a shaft, inflatable bladder disposed at an end of the shaft where the bladder has an inflatable shape selected from the group consisting of circular, oval, eccentric, oblong, conical, wedge-shaped, V-shaped and multiple lobes, along with other features. Claim 11 of the instant application recites a retractor comprised of a shaft and an inflatable bladder that is eccentric or eccentrically mounted on the shaft. Furthermore, claims 13-15 of the instant invention are identical to claims 4-6 of copending Application No. 10/729,634, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7 of copending Application No. 10/743,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 7 of copending Application No. 10/743,192. The combination of claims 1 and 7 disclose a similar retractor of the instant invention differing only in the shape of the inflatable bladder. Furthermore, claims 13-15 of the instant invention are identical to claims 2-4 of copending Application No. 10/743,192, respectively.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15-21 of copending Application No. 10/729,768 (Note: Claims 15-21 refer to the most recent claim amendment on file in Application No. 10/729,768 - filed July 1, 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claim 1 and 21 of copending Application No. 10/729,768. Claim 1 of copending Application No. 10/729,768 recites an apparatus comprised of a shaft and an inflatable bladder wherein the inflatable bladder has a shape selected from the group consisting of: eccentric, conical and wedge-shaped, along with other features. Claims 13-15 are identical to claims 16-18 of copending Application No. 10/729,768, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,071,406 to Jang in view of U.S. Patent No. 4,295,464 to Shihata.

Application/Control Number: 10/743,125

Page 5

Art Unit: 3739

In regard to claims 11, 25 and 28-29, Jang discloses a retractor comprising: a shaft 50 including at least one flexible portion (see Col. 4, Lines 67-68); a plurality of inflatable bladders 42, 62 partially circumscribing an outer surface of the shaft (see Figs. 2-5 and Col. 11, Lines 57-60), at least one of the inflatable bladders being disposed adjacent to the at least one flexible portion of the shaft (see Col. 6, Lines 10-25) and being configured to cause at least a section of the at least one flexible portion of the shaft to become more rigid when the at least one inflatable bladder is inflated (see Col. 9, Lines 40-46). Jang is silent with respect to a cannula having a passage which receives the shaft to deploy the bladder at a target site in tissue. Shihata teaches of an analogous apparatus having a cannula 102 which has a passage that receives a catheter 101 therethrough. It would have been obvious to one skilled in the art at the time the invention was made to use a cannula with the apparatus of Jang to aid in placing the shaft at a desired site within the body as taught by Shihata.

In regard to claim 12, Jang discloses a retractor, wherein the at least one inflatable bladder is shaped so that it expands into an eccentric shape when inflated by fluid pressure introduced through the shaft (see Figs. 3-5 and Col. 11, Lines 40-41).

In regard to claim 13, Jang discloses a retractor, wherein the at least one inflatable bladder does not substantially stretch when fully inflated (see Col. 9, Lines 40-42).

In regard to claims 14-15, Jang discloses a retractor, wherein the at least one inflatable bladder operates at inflation pressure from 10 mmHG to 1000 mmHG (see Col. 10, Lines 1-6).

In regard to claims 22 and 26, Jang discloses a retractor, wherein the plurality of inflatable bladders is eccentrically mounted on the shaft (see Figs. 3-5 and Col. 11, Lines 40-41).

In regard to claim 23, Jang discloses a retractor, wherein the plurality of inflatable bladders includes at least two inflatable bladders that abut each other (see Col. 6, Lines 10-11).

In regard to claims 24 and 27, Jang discloses a retractor, wherein the plurality of inflatable bladders is axially spaced along the shaft (see Figs. 2, 7, 11 and 15).

Response to Arguments

Applicant's arguments with respect to claims 11-15 and 22-29 have been considered but are most in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./ Examiner, Art Unit 3739 /Linda C Dvorak/ Supervisory Patent Examiner, Art Unit 3739